

Docket No. 97N-0217

PROPOSALS TO INCREASE THE AVAILABILITY OF APPROVED ANIMAL DRUGS FOR MINOR SPECIES AND MINOR USES.

I support any and all efforts by FDA to facilitate approvals for minor use animal drugs. 97-15 P2:58

MODIFICATION OF EXTRALABEL PROVISIONS

Since medicated feed is the only practical method of treating diseases for aquaculture species, modification of the extralabel provisions would greatly benefit aquaculture producers. In particular FDA approved antibiotics for aquaculture which are limited either to specific species and specific diseases cannot be used for other aquaculture species and other diseases, would benefit if extralabel use is allowed.

A sunset period is a good idea and people should realize this is only a temporary situation. Besides efforts are under way to pursue new drug approvals.

The proposed modification should also include reproductive hormones and implants.

REMOVAL OF DISINCENTIVES

I'm not sure if the suggested strategies are sufficient in removing the regulatory disincentives, but they certainly are a step in the right direction. I also support a Minor Use Advocate within the Office of Surveillance and Compliance.

ENHANCEMENT OF EXISTING PROGRAMS FOR DATA DEVELOPMENT

Perhaps within the Regional Aquaculture Centers, if all of the funds Congress appropriated were allocated those additional monies could be used as seed money to attract matching funds from other sources.

INCENTIVES TO PURSUE MINOR DRUG APPROVALS

I believe the benefit of extended exclusivity outweighs the potential increased drug costs that could be associated with decreased competition from generic approvals.

It probably would be a more significant incentive to provide for an extended period of exclusivity for all the claims of the product.

DATA SHARING BY MAJOR SPECIES NADA HOLDERS

It should be up to each individual company whether to share or not to share data. Its unfair to require sharing of data. It should be voluntary.

If a company volunteers to share data, the minor use applicant can sign an agreement

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releasing the pioneer from liability.

CREATION BY STATUTE OF A “MINOR USE ANIMAL DRUG” PROGRAM

Based on the success of the “human orphan drug” program and the scarcity of minor use drugs, a “minor use animal drug” program has good potential to increase the number of approved minor use drugs.

Yes, the proposed incentives are necessary for this program.

CONDITIONAL DRUG APPROVAL FOR MINOR USES INVOLVING NON-FOOD ANIMALS

The proposed constraints seem to be sufficient to provide consumer protection and it should be restricted to non-food animals only. However, as FDA recognizes, there are early life stages of food producing animals that are normally not used for food (particularly aquaculture species) and as long as FDA’s criteria are met, these early life stages should be considered non-food animals.

ALTERNATE APPROVAL STANDARD/EXPERT REVIEW PANELS FOR MINOR USES INVOLVING NON-FOOD ANIMALS

Yes, I believe animal caretakers will find this proposal acceptable, that they have the necessary expertise for the ERP panels, and that its appropriately restricted to non-food animals. However, as FDA recognizes, there are early life stages of food producing animals that are normally not used for food (particularly aquaculture species) and as long as FDA’s criteria are met, these early life stages should be considered non-food animals.

INTERNATIONAL HARMONIZATION

Yes, non-governmental input can facilitate equivalency determinations. There are sufficient foreign approvals to justify such a program. Minor uses should be included in international harmonization program.

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